

INDEPENDENT REVIEWERS OF TEXAS, INC.

2150 S. Central Expressway · Suite 200-264 · McKinney, Texas 75070

Office 214-533-2864 Fax 214-380-5015

e-mail: independentreviewers@hotmail.com

Notice of Independent Review Decision

[Date notice sent to all parties]:

03/30/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: 4 lead TENS unit purchase

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Board Certified PMR and Pain Management

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

X Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female whose date of injury is xx/xx/xx. The patient was driving when she was thrown forward. X-rays of the left hip dated 09/10/13 revealed no gross acute bony abnormality. Note dated 02/17/15 indicates compensable diagnosis is post laminectomy syndrome of the lumbar spine. The TENS unit has been previously prescribed and dispensed. The inability to obtain the unit poses long-term functional capabilities and beneficial in reducing back pain. The remainder of the submitted records are handwritten notes and laboratory reports.

Initial request for 4 lead TENS unit purchase was non-certified on 02/13/15 noting that the reference does not provide any data to support an expectation that utilization of the requested piece of durable medical equipment would be expected

to enhance long-term functional capabilities. The denial was upheld on appeal dated 02/24/15 noting that the clinical documentation submitted for review indicated that the TENS unit requested was not for a one month trial, but was for purchase. Although the documentation submitted did indicate the patient is no longer taking medications, the documentation did not provide evidence that the TENS unit would not be used as an adjunct to a program of evidence based conservative care.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Based on the clinical information provided, the request for 4 lead TENS unit purchase is not recommended as medically necessary, and the two previous denials are upheld. This patient's date of injury occurred over 21 years ago. There is no comprehensive assessment of treatment completed to date or the patient's response thereto submitted for review. There is no current, detailed physical examination submitted for review. The patient has previously been dispensed a TENS unit; however, there are no objective measures of improvement documented to establish efficacy of treatment and support purchase of the unit. There are no specific, time-limited treatment goals provided. The Official Disability Guidelines note that TENS is not generally recommended for the treatment of chronic low back pain as there is strong evidence that TENS is not more effective than placebo or sham.

IRO REVIEWER REPORT TEMPLATE -WC

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

**X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE
IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

**X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT
GUIDELINES**

ODG Low Back Chapter

TENS (transcutaneous electrical nerve stimulation)

Not recommended as as an isolated intervention, but a one-month home-based TENS trial may be considered as a noninvasive conservative option for chronic back pain, if used as an adjunct to a program of evidence-based conservative care to achieve functional restoration, including reductions in medication use.

Acute: Not recommended based on published literature and a consensus of current guidelines. No proven efficacy has been shown for the treatment of acute low back symptoms. (Herman, 1994)

(Bigos, 1999) (van Tulder, 2006)

Chronic: Not generally recommended as there is strong evidence that TENS is not more effective than placebo or sham. (Airaksinen, 2006) There is minimal data on how efficacy is affected by type of application, site of application, treatment duration, and optimal frequency/intensity. (Brousseau, 2002) There are sparse randomized controlled trials that have investigated TENS for low back pain. One study of 30 subjects showed a significant decrease in pain intensity over a 60-minute treatment period and for 60 minutes after. (Cheing, 1999) A larger trial of 145 subjects showed no difference between placebo and TENS treatment. (Deyo, 1990) Single-dose studies may not be effective for evaluating long-term outcomes, or the standard type of use of this modality in a clinical setting. (Milne-Cochrane, 2001) (Sherry, 2001) (Philadelphia Panel, 2001) (Glaser, 2001) (Maher, 2004) (Brousseau, 2002) (Khadikar, 2005) (Khadikar2, 2005) Although electrotherapeutic modalities are frequently used in the management of CLBP, few studies were found to support their use. Most studies on TENS can be considered of relatively poor methodological quality. TENS does not appear to have an impact on perceived disability or long-term pain. Highfrequency TENS appears to be more effective on pain intensity when compared with low frequency, but this has to be confirmed in future comparative trials. It is also not known if adding TENS to an evidence-based intervention, such as exercise, improves even more outcomes, but studies assessing the interactions between exercise and TENS found no cumulative impact. (Poitras, 2008) For more information, see the Pain Chapter.

Recent research: A recent meta-analysis concluded that the evidence from the small number of placebo-controlled trials does not support the use of TENS in the routine management of chronic LBP. There was conflicting evidence about whether TENS was beneficial in reducing back pain intensity and consistent evidence that it did not improve back-specific functional status. There was moderate evidence that work status and the use of medical services did not change with treatment. Patients treated with acupuncture-like TENS responded similarly to those treated with conventional TENS. (Khadikar-Cochrane, 2008) On June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) issued an updated decision memo concluding that TENS is not reasonable and necessary for the treatment of chronic low back pain based on a lack of quality evidence for its effectiveness. Coverage is available only if the beneficiary is enrolled in an approved clinical study. (Jacques, 2012)